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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,892	05/29/2001	Stephen Christopher Porter	8600-0015	5581

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EXAMINER	
IZAGUIRRE, ISMAEL	
ART UNIT	**PAPER NUMBER**
3765	

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/866,892	PORTER, STEPHEN CHRISTOPHER	
	Examiner	Art Unit	
	Ismael Izaguirre	3765	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,9,11,14-17,19,24,26-33,35,37,40-43 and 45-49* is/are rejected.

7)☒ Claim(s) *8,10,12,13,18,20-23,25,34,36,38,39 and 44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The examiner is appreciative of the changes made to the language of the claims. These have been duly noted and considered.

CLAIMS

Summary

Claims 1 and 27 are the independent claims under consideration in this Office action.

Claims 3-26 and 28-49 are the dependent claims under consideration in this Office action.

Applicant is asked to note the newly found prior art (Truckai et al.) as applied below. Concerning the patentability of the claims, the following is submitted for applicant's consideration:

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27,30-33,35,37,40-43,45 and 46 are rejected under 35 U.S.C. § 102(e) as being anticipated by Truckai et al. (6,458,127).

Truckai et al. teach a vaso-occlusive device useful for occluding an aneurysm comprising a polymeric occluder. Truckai et al. teach the biocompatible polymeric occluding device 12 as comprising a three dimensional shape. Truckai et al. teach a generally cylindrical shape and more specifically, an oval or flattened shape (column 5, lines 55-56), however, other shapes are acceptable. The occluder is formed into the above noted three dimensional shape and is adapted to be deployed into the body cavity while retaining the three dimensional shape during the deployment procedure, which includes feeding the occluder through a longitudinal passage in the catheter 5 (see figures 1 and 2).

The occluder includes filaments along the longitudinal axis thereof (see figure 9, for example) where in on embodiment the micro filaments 350 (same figure) are arranged along the cross section of the such that at the outer surface of the occluder, the filaments form channels with the outer surface along the longitudinal axis. Further, Truckai et al. teach an embodiment where the polymer or a metallic coating thereon can be formed in a spiraled or coiled shape (column 10, lines 54-56) and this would include channels between the coils perpendicular to the longitudinal axis of the occluder.

Truckai et al. teach the device, which includes the occluder, as being insertable and movable along the catheter by a pusher means 24 (figure 3), where in one embodiment part of the device i.e., the pusher, includes mechanical means (barbs 57, figure 3, for example) for moving the occluder and forming a separable junction with the

occluder. The barbs 57 are micro-machined, or more specifically, taught as cut (column 7, line 57) for gripping and guiding the occluder, and forming the separable junction with the occluder.

The occluder is taught as being formed of a single-molded element consisting of at least two separate elements with a plurality of shaped structures linked in series. Specifically, the occluder has spherical shaped elements 360 (see figure 10) connected in series along the length of the occluder by the polymer matrix.

The occluder is guided along the passage of the catheter and is located in the final desired position (see figures 6A and 6B). The occluder includes a metallic coating or microfibers, which are electrically conductive. The occluder is energized and heats up so as to coagulate the surrounding tissue and fluids, which encourage healing and sealing the defect. Further, the occluder is energized by a second amount there localized heating occurs and the desired portion of the occluder is separated from an occluder portion inside the catheter (column 3, lines 33-45). The desired position of the occluder within the vessel is located with the aid of fluoroscopy where the occluder is provided with a radio-opaque material, such as BiO3, and then the occluder is used to fill the aneurysm and cut to the desired length by the above noted electrical energy, heat energy (caused by the electrical current) and mechanical mean (the separable junction including barbs) and the catheter is withdrawn.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,3-7,9,11,14-17,19,24,26,28,29 and 47-49 rejected under 35 U.S.C. § 103(a) as being unpatentable over Truckai et al. in view of Cooper '884.

Truckai et al. disclose the invention substantially as claimed. See above for specific explanations of the structural details of this document. Briefly, Truckai et al. teach a vaso-occlusive device useful for occluding an aneurysm comprising a polymeric occluder. Truckai et al. teach the biocompatible polymeric occluding device 12 as comprising a three dimensional shape. Truckai et al. teach a generally cylindrical shape and more specifically, an oval or flattened shape (column 5, lines 55-56) however, other shapes are acceptable. The occluder is formed into the above noted three dimensional shape and is adapted to be deployed into the body cavity while retaining the three dimensional shape during the deployment procedure, which includes feeding the occluder through a longitudinal passage in the catheter 5 (see figures 1 and 2). Truckai et al. Teach that a current is passed through the occluder for forming coagulum on the vicinity of the occluder (figure 6C, for example). However, Truckai et al. do not firstly, suggest the polymer occluder as being an absorbable polymer formed of poly-L-lactide, and secondly, not bioactive and thirdly, not being formed by injection molding.

Cooper teaches the making and use of biocompatible absorbable polymeric three dimensionally shaped medical devices. Cooper teaches (in column 2, lines 43-45) the surgical devices formed of a polymer and including vascular implants formed of absorbable polymers with improved visibility, such as amorphous polylactide (including D-lactide, L-lactide and mixtures thereof).

It would have been obvious to a person having ordinary skill in the art at the time of Applicant's invention to construct the occluder of Truckai et al. as including polymers formed of poly-L-lactide. Providing such a polymer with good in vivo properties (Cooper- column 1, line 31) would enhance the healing of the patient by providing a polymer, which is absorbed by such patient, and provide a further visual cue to aid the surgeon in locating the implant within the occludable portion of the vessel.

Cooper teaches the forming and use of biocompatible absorbable polymeric three dimensionally shaped medical devices. Cooper teaches (in column 2, lines 43-45) the surgical devices formed of a polymer and including vascular implants formed of absorbable polymers and further teaches that these implants are formed by use of injection molding or extrusion molding equipment (column 4, lines 40-43).

It would have been obvious to a person having ordinary skill in the art at the time of Applicant's invention to construct the extruded occluder (column 2, line 29) of Truckai et al. as including polymers formed by the process of injection molding. Providing such a molded structure would assure a precisely formed and properly shaped desired profile for the occluder.

Cooper teaches the forming and use of biocompatible absorbable polymeric three dimensionally shaped medical devices. Cooper teaches (in column 2, lines 43-45) the surgical devices formed of a polymer and including vascular implants formed of absorbable polymers and further teaches that these implants are formed of a polymer which is bioactive and includes blends of other materials therein, such as therapeutic agents. The therapeutic agents comprise antibiotics, and antiviral agents, for example (see column 5, lines 4-55).

It would have been obvious to a person having ordinary skill in the art at the time of Applicant's invention to construct the extruded occluder (column 2, line 29) of Truckai et al. as including polymers formed by the process of blending therapeutic agents within the matrix. Providing such agents allows the administering of such drugs to the patient. Upon contact with body fluids, the polymer undergoes gradual degradation, and this would allow the comitant release of the dispersed drug for a sustained or extended period (from column 5, lines 4-55 and specifically, lines 47-55).

Remarks

Applicant will note the re-application of the Cooper/ Palermo documents. The rejection however has been reconfigured for purposes of clarity and in response to applicant's remarks. The following is submitted for applicant's consideration:

Claims 27-32,40,42,45, 47 and 48 rejected under 35 U.S.C. § 103(a) as being unpatentable over Cooper '884 in view of Palermo '173.

Cooper discloses the invention substantially as claimed (applicant is also asked to note further Cooper structure noted above in the Truckai et al./ Cooper rejection, as

well as what follows). Cooper teaches the making and using of implantable medical devices. The devices are biocompatible and absorbable (column 1, line 63, for example) polymeric three-dimensional injection molded (column 4, line 43, for example) medical devices (col. 4, lines 41-53). As exemplary, Cooper teaches forming vascular implants of such polymeric material. Cooper teaches the medical implant as being bioactive (see above), injection molded and including three-dimensional shapes, such as a tube, for example (column 4, line 64). However, Cooper does not firstly suggest the vascular implants as including channels and such channels being perpendicular to the longitudinal axis of the implant, and secondly, as not including a severable mechanical joint between the pusher and implant and thirdly, not being formed as including a radio-opaque material.

Palermo teaches a vessel occluding system including a catheter system for feeding and directing a vascular implant into a vessel for occluding the vessel. Palermo teaches an occluder 10 comprising a cylindrical configuration having a longitudinal axis and further that the occluder is formed with a coil structure (column 3, line 18, for example). As such, the coil structure includes channels along its longitudinal direction transverse to the longitudinal direction.

It would have been obvious to a person having ordinary skill in the art at the time of Applicant's invention to construct the vascular implant of Cooper as including a coil shape instead of a tube shape. Providing a coil, which in itself is considered a modified tube, would have allowed the easier passing of such occluder through a catheter and

able to more easily adapt and bend to the curves in the vasculature due to the channels between the coils in said transverse direction.

Palermo teaches a vessel occluding system including a catheter system for feeding and directing a vascular implant into a vessel for occluding the vessel. Palermo teaches an occluder 10 comprising a cylindrical configuration having a longitudinal axis which is fed through the catheter and pushed along with a pusher having a mechanical joint 16, 17 (figure 3C, for example). The mechanical joint connects and pushes the occluder through the catheter and vessel for the proper placement of the occluder and releases the occluder when the desired position is obtained.

It would have been obvious to a person having ordinary skill in the art at the time of Applicant's invention to construct the vascular implant of Cooper as including a coil shape instead of a tube shape. Providing a coil, which in itself is considered a modified tube, would have allowed the easier passing of such occluder through a catheter and able to more easily adapt and bend to the curves in the vasculature due to the channels between the coils in said transverse direction.

Palermo teaches a vessel occluding system including a catheter system for feeding and directing a vascular implant into a vessel for occluding the vessel. Palermo teaches an occluder 10 comprising a cylindrical configuration having a longitudinal axis, which is fed through the catheter and pushed along with a pusher. The movement and location of the occluder is located within the vasculature, by the surgeon by use of a fluoroscope (column 9, line 26), since it includes a radio-opaque material or an x-ray contrast material (column 1, line 41).

It would have been obvious to a person having ordinary skill in the art at the time of Applicant's invention to construct the vascular implant of Cooper as including a radio-opaque material. Providing such a material would allow the proper feeding and placement of the vascular implant of Cooper in the intended location within the vessel.

Remarks

Applicant has argued that Cooper does not teach vaso-occlusive elements since "vascular implants" (as taught by Cooper) is not a vaso-occlusive device. The examiner notes that Cooper does teach an occluder since it is considered a vascular implant. In fact, Applicant admits this to be true since he discloses that "vaso-occlusion devices are surgical implements or implants that are placed within the vasculature of the human body..." See the specification lines 16-17. Accordingly, Cooper as modified by Palermo remains applicable to the above noted claims.

ALLOWABLE SUBJECT MATTER

Claims 8,10,12,13,18,20-23,25,34,36,38,39 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

PERTINENT CITATIONS

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wallace et al. Illustrate an occluder including an inner core covered by a polymer. Engelson illustrates a polymeric coating on a vaso-occlusive element.

INQUIRIES

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ismael Izaguirre whose telephone number is (571) 272-4987. The examiner can normally be reached on M-F (8:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on (571) 272-4983. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ismael Izaguirre
Primary Examiner
Art Unit 3765

II
1/13/05